MTPConnect
MedTech and Pharma Growth Centre

MTPConnect REDI Program Skills Gap Analysis

INTERIM REPORT

NOVEMBER 2020

Australian Government
Department of Industry, Science, Energy and Resources
Industry Growth Centres

Acknowledgments

MTPConnect would like to acknowledge the REDI Steering Committee, MTPConnect Board and all sector stakeholders who provided their valuable inputs that have informed this report. MTPConnect also thanks L.E.K. Consulting for its assistance in preparing the document.

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1. INTRODUCTION AND CONTEXT

MTP sector landscape

The medical technologies, biotechnologies and pharmaceuticals (MTP) sector is critical to Australia's economy, the health outcomes of the population and the innovation ecosystem. There were nearly 1,300 companies in the MTP sector, which employed approximately 68,000 workers and contributed $5.2 billion in Gross Value Added to the economy in 2019.[1] The sector enables access to innovative therapies and medical devices that assist in the diagnosis, treatment and monitoring of disease, delivering significant benefits to patients and improving overall population health outcomes.

The MTP value chain encompasses a wide range of participants, each playing a critical role in the sector's growth and success. The value chain extends from research where discoveries and inventions are made, to pre-clinical and clinical development and to manufacturing and market launch of products. This value chain comprises of consumers and patients, clinicians, universities, SMEs, multinational companies, investors, service providers, industry organisations, regulators, policymakers and others involved in healthcare delivery.

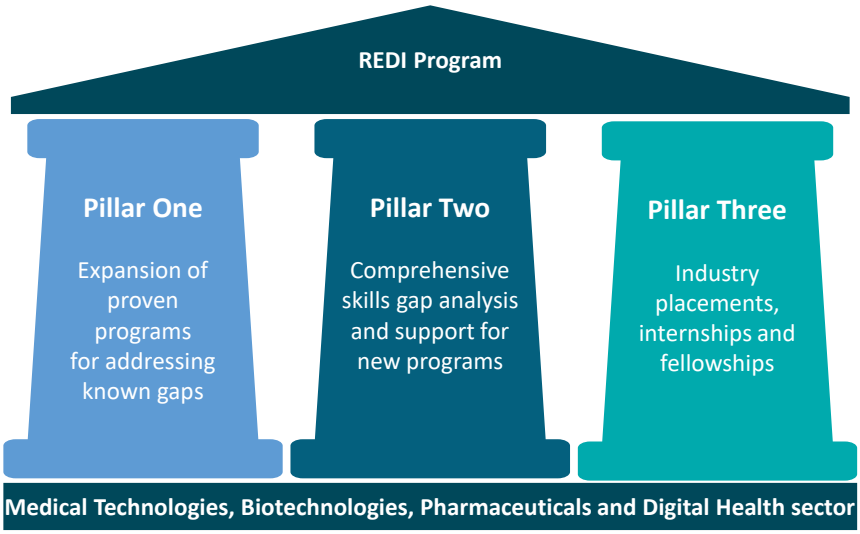
MTPConnect is an independent, not-for-profit Growth Centre established in 2015 to drive connectivity, innovation, productivity and competitiveness in Australia's MTP sector.

Context for this report

In May 2020, MTPConnect was contracted by the Australian Federal Government to operate the Researcher Exchange and Development within Industry (REDI) program. This program is a four-year, $32 million initiative funded by the Medical Research Future Fund (MRFF) that aims to deliver system-wide improvements to skills development and training programs for the MTP workforce.

In delivering the REDI program, MTPConnect will partner with research, training and industry organisations to deploy an integrated three-pillar plan driving skills development and workforce training for the MTP sector nationally. The figure below illustrates the three pillars of the REDI program.

[1] MTPConnect Sector Competitiveness Plan 2020, April 2020



As a key foundation for the second pillar, MTPConnect is conducting a comprehensive 'root-and-branch' review of current and future skills gaps. Addressing the gaps which are identified will help to prepare a future-ready workforce that will support and drive the growth of the Australian MTP sector,competing at a global scale. The scope of this skills gap analysis does not extend to end-users, consumers and front-line health workers such as patients, doctors, nurses or allied health professionals.

This skills gaps review is being conducted in three phases. This first interim report identifies skills gaps that need to be addressed across the sector as a near-term priority. These priority skills gaps are those that can unlock significant value for the MTP sector if addressed, impact a broad cross-section of the MTP sector value chain, are not currently addressed by existing REDI programs and can be reasonably addressed within the next 12 – 18 months. It is anticipated that a contestable (RFP) program will be undertaken to identify providers who can deliver new programs to address these initial priority skills gaps. The RFP process will be open to broad range of education and training groups, including those outside of MTPConnect's core partners. Based on the skills gaps identified in this report, MTPConnect will be developing learning outcomes and competencies in order to inform this first round of Pillar Two RFPs.

The second phase of this analysis, to be completed by February 2021, will identify a broader and more comprehensive set of skills gaps across the sector that need to be addressed in order to drive continued sector growth in the future. The final report will address a set of skills gaps that are broader than can be addressed through the REDI program directly and will help inform opportunities for other programs to be deployed.

Beginning in July 2021, an update of the skills gap analysis will be undertaken to ensure newly emerging gaps are identified and addressed by implementing new programs. In this third phase of the skills gap analysis, a Refresh Report to be finalised in September 2021.

In identifying the skills gaps in this interim report, we have taken into account global megatrends that are shaping the sector over the long term and MTPConnect's sector vision and priorities. These factors are outlined in the sections that follow.

Like the rest of the economy, the MTP sector has been significantly impacted by the COVID-19 pandemic. While the MTP sector has been instrumental in Australia's positive response, the pandemic has brought to light skills gaps and capabilities that will need to be addressed to better position Australia for future pandemics. This interim report also takes into account the skills gaps that have been highlighted during our national response to COVID-19.

Global megatrends

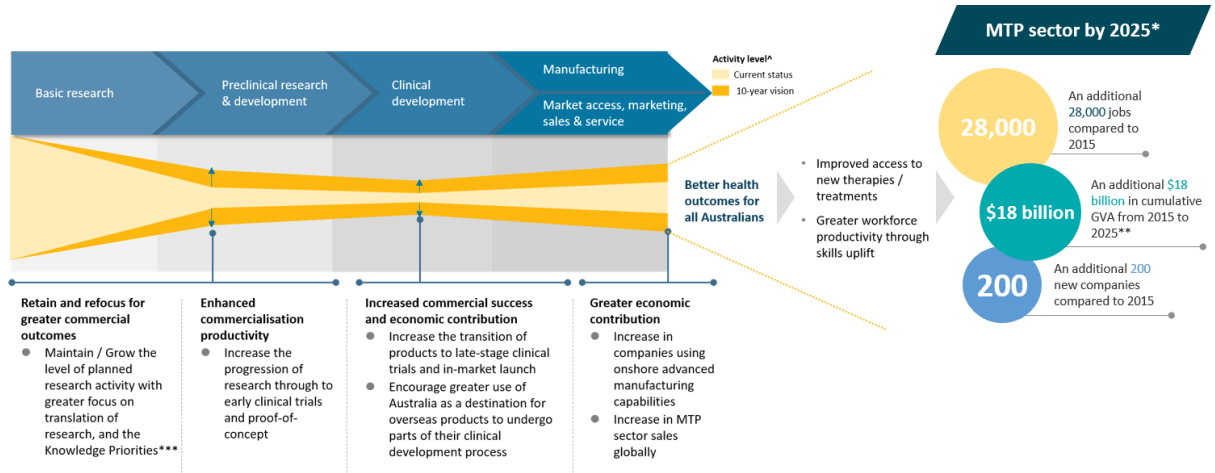
There are nine global megatrends that are shaping the sector over the long-term, as identified in the MTP 2020 Sector Competitiveness Plan. [1] These global megatrends, illustrated in the figure below, are overarching social, economic, environmental, technological and geopolitical forces that can be expected to present new opportunities and challenges for the sector.

These megatrends will shape the skills and capabilities required of the future workforce globally and in Australia. Central to all of the megatrends is digital evolution. The rapid evolution of digital technologies will have a substantial impact on the MTP sector as data can increasingly be generated, processed and exchanged in real time and at greater scale. This megatrend will create growing need for data scientists, software engineers, cyber-security and data privacy experts, digital product designers and Artificial Intelligence experts who have knowledge of the MTP sector and its intricacies. It is critical for Australia to consider these factors in order to maintain and further enhance its global reputation and competitive position in the MTP sector. Further details on these megatrends and the implications and opportunities for the MTP sector can be found in the 2020 Sector Competitiveness Plan.[1]

MTP sector vision and priorities

In order to continue providing optimal health outcomes for Australians and driving economic and jobs growth over the next 10-20 years, MTPConnect has articulated its vision and growth priorities for the MTP sector.

MTPConnect's vision for the sector is to maintain and grow planned levels of expenditure in R&D to deliver greater success in translation and commercialisation, creating more products that reach proof-of-concept and early-stage commercialisation.[1]



Note: * The 2024 estimates developed by MTPConnect in 2016 assume that the decline in GVA, employment and companies over the 2010-2015 period can be reversed, with the industry returning to 2010 levels by 2020 and then continuing to grow at an equivalent rate out to 2025. This scenario reflects the full potential of the government's incremental investment in the sector including MTPConnect, the BTF, and the MRFF;
** Compared to the baseline forecast
*** These are areas of high unmet need and in which a sizeable commercial opportunity exists, where Australia can develop world-class research excellence;
^ Activity level includes all forms of activity and economic value creation in Australia regardless of whether it originates from Australia or overseas. Diagram is intended to be illustrative only and is not to scale

MTPConnect identified seven 'sector priorities' that underpin the achievement of the above-mentioned sector vision for enhanced healthcare and economic outcomes for Australia. These sector priorities have been refined over the past five years (2016-2020) and outline attributes that ensure Australia can enhance its global competitiveness.[1]

Sector Priorities

Priority 1	Align investment in Knowledge Priorities that meet current and future market needs
Priority 2	Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials
Priority 3	Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies
Priority 4	Strengthen Australia as an attractive clinical trial research destination
Priority 5	Support the development of digital healthcare solutions, devices and data analytics
Priority 6	Position Australia as a preferred partner for international markets
Priority 7	Support advanced manufacturing as a part of the broader Australian innovation system

One of the key success factors to achieving the sector vision will be ensuring that the MTP sector workforce is equipped with the skills and capabilities required to address these sector priorities. This will include ensuring the MTP workforce is of a sufficient size and has the right training / skills-development required for success.

The following chapter presents the methodology used to identify an interim list of priority skills gaps, and provides a description of the three immediate priorities to be addressed within the REDI program.

2. IDENTIFICATION OF PRIORITY SKILLS GAPS

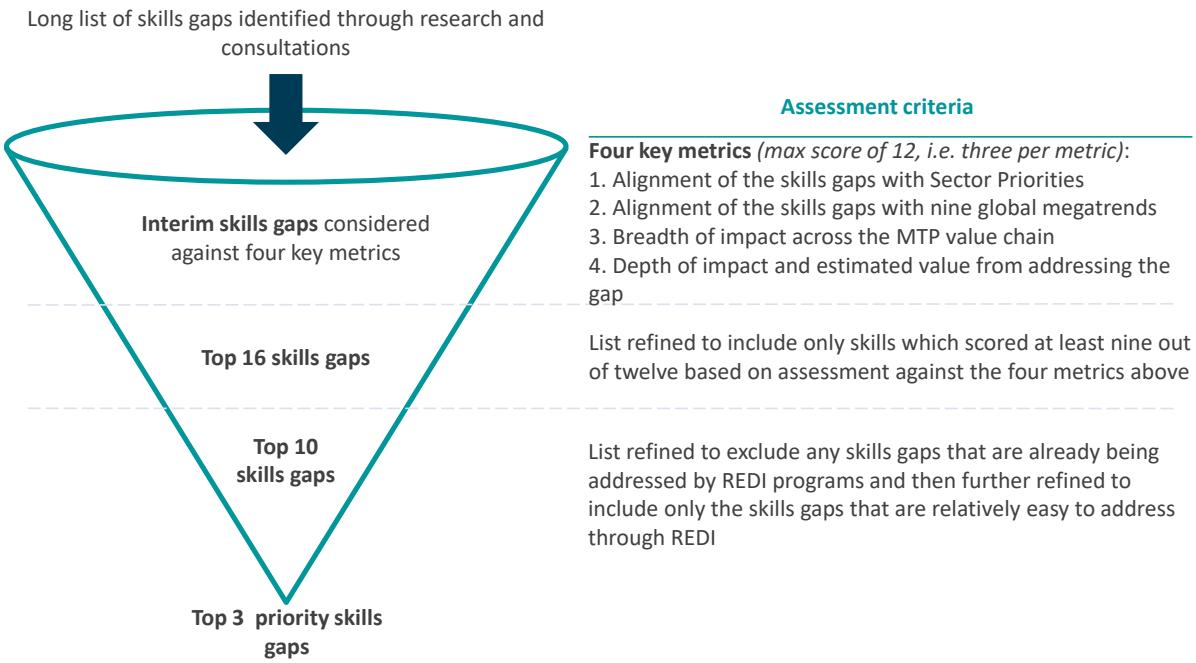
Methodology

In this first phase, an interim list of skills gaps across the MTP sector was identified through extensive desktop research and a set of 46 targeted stakeholder consultations spanning different parts of the MTP value chain. The report also leverages the workforce skills and capacity review undertaken by MTPConnect in July 2020 which surveyed 121 respondents with hiring responsibilities (such as HR personnel) from across the sector.[2]

The identified skills gaps have been organised under key 'skills development themes' and further assessed on this basis. These themes spanned several core aspects of the MTP sector and the value chain, including specialist & technical skills, product development & commercialisation, health data and cyber security, communication skills, clinical trials, health economics & regulatory affairs and advanced manufacturing & supply chain.

The highest priority skills gaps were identified by assessing four key metrics outlined in the prioritisation framework below. In order to arrive at a shortlist of three priorities, consideration was also given to whether identified skills gaps were already targeted by existing REDI initiatives and to the relative ease of addressing each initiative in a 12 to18 month period. Further information on the assessment and prioritisation of the skills gaps against each component of the framework can be found in Appendix 1 and 2.

Prioritisation Framework



[2] A survey of workforce skills and capacity in the medical technology, biotechnology, pharmaceutical and digital health (MTP) sector (undertaken for MTPConnect), Monash University, July 2020

Priority skills gaps across the MTP sector

The table below highlights the 16 skills gaps that received a score greater than 9 out of 12 when assessed against the prioritisation framework. The skills gaps highlighted in yellow represent the ten gaps that are not already being addressed through REDI.

Skills development theme	Specific priority skills gaps
Advanced manufacturing & supply chain	Understanding of quality management, protocols and systems
Health data & cyber security	Capability gap in design and use of AI within MTP
	Big data capture, management and analysis capability
	Leadership awareness about the importance and best-practice management of cyber security
Product development & commercialisation skills	Shortage of industry professionals with end-to-end translational experience
	Identifying unmet market need and understanding the clinical context
	Entrepreneurial mindset & risk tolerance
	Understanding the payer and the reimbursement pathway and requirements
	Understanding of end-to-end product development pathways
	Expertise in IP strategy and pathways
	Expertise in product design including understanding of the end-user
Clinical trials	Strategic clinical trial design to address regulatory and payer needs
Communication skills	Procuring investment, funding and / or industry collaboration
Specialist & technical skills	Lack of clinical and technological capability in genomics and other '-omics'
	Shortage of pharmacologists and toxicologists
Health economics & regulatory affairs	Expertise in health economics, particularly across medtech and digital health

Key: Top ten skills gaps

Each of the ten shortlisted skills gaps were then assessed for relative ease of establishing programs through REDI that could effectively address the gap within the four-year term of the program. The following table outlines the ten shortlisted skills gaps in more detail, with the three highlighted in blue identified as the top priority gaps for the sector that are to be addressed by new programs in the first round of REDI, Pillar Two RFPs.

Skills development theme	Specific priority skills gaps	Brief description
Advanced manufacturing & supply chain	Understanding of quality management, protocols and systems	Understanding and implementation of quality assurance and control protocols, particularly relating to manufacturing of therapeutics and devices (including GLP, GCP, GMP guidelines and ISO standards). This also extends to quality control practices relating to data collection
Health data & cyber security	Capability gap in design and use of AI within MTP	Skills in designing and using AI technologies for advanced healthcare applications (e.g., for diagnosis or decision-making), complementing physicians' skills, increasing productivity and improving patient care
	Big data capture, management and analysis capability	Data scientists who can capture, curate and interpret large streams of unstructured health data, e.g., in real-world evidence trials
	Leadership awareness about the importance and best-practice management of cyber security	Skills at the organisation leadership level relating to the importance of cyber security and best-practice management required to protect organisations from cyber attacks
Clinical trials	Strategic clinical trial design to address regulatory and payer needs	Skills in designing clinical trials for commercial success at the outset with understanding of regulatory and reimbursement approval requirements, specifically applicable to SMEs
Specialist & technical skills	Lack of clinical and technological capability in genomics and other '-omics'	Specialist skillset in genomics and other '-omics' (e.g., proteomics and metabolomics), including the management and analysis of large biological data banks
	Shortage of pharmacologists and toxicologists	Specialist skillsets in pharmacology (studying how medicines interact with cells and tissues to predict effects in humans) and toxicology (studying adverse effects of medicines in-vivo, legally required for preclinical studies)
Product Development and Commercialisation	Shortage of industry professionals with end-to-end translational experience	Capacity gap of experienced professionals who have practical translational experience and can mentor researchers/start-ups through the research translational process, including early-phase drug development
	Understanding of end-to-end product development pathways	Capacity gap of professionals with experience and holistic understanding of what needs to be done to develop a product and take to market, especially in medtech. This includes but is not limited to iterative product design, awareness of regulatory, reimbursement requirements and identification of manufacturing partners
Health economics & regulatory affairs	Expertise in health economics, particularly across medtech and digital health	Ability of health economists to appropriately evaluate and assess the cost-effectiveness and economic impacts of new medtech and digital health products, in order to support reimbursement submissions

Key: Top priority skills gaps

Each of the three identified priority skills gaps is discussed in further detail below. To the extent possible, they have been characterised according to their underlying nature and whether they stem from capacity, capability and / or structural issues, such as a lack of appropriate infrastructure or policy incentives.

Priority Skills Gap One: Understanding of quality management systems and protocols

Theme: Advanced Manufacturing and Supply Chain

Overview

Products in the MTP sector are highly regulated. Manufacturers must meet relevant quality standards before they are eligible to seek approval from government regulators such as the TGA and FDA. Applicable international quality standards for manufacturers of pharma / biotech and medtech products include Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and also ISO9001, ISO13485, ISO17025 and ISO27001. ISO27001 establishes requirements related to information security management systems which is especially important for businesses that capture patient data. In addition, Good Clinical Practice (GCP) is an international quality standard for conducting clinical trials that would apply to sponsors, service providers and hospitals running clinical trials. Being accredited, or at least aligned with relevant industry standards, represents a mark of assurance regarding the competence of an organisation and the integrity, reliability and consistency of its products.

Stakeholder consultations have highlighted that universities, startups and SMEs within the MTP sector often lack the following skills related to quality management:

- Understanding of the importance of adopting and maintaining appropriate quality management systems among business leaders; and
- Lack of staff members with sufficient training in quality management systems to:
    - Define best-practice quality management principles and protocols that are aligned to relevant industry standards;
    - Design and implement a path for achieving greater alignment to industry accreditation; and
    - Maintain quality procedures and quality systems to ensure high standard facilities

Although it is a core capability for commercial success in the MTP sector, adoption of systematic quality management processes and maintaining alignment with accreditations often can be considered to be time-consuming and too difficult.

Stakeholders impacted

Large pharma and medtech companies tend have sufficient in-house capabilities due to their scale and deep knowledge of the regulatory requirements of the sector. However, the skills gap is particularly evident within startups and SMEs across the pharma / biotech and medtech sectors. Emergence of digital health businesses has also brought to light the lack of understanding of ISO27001 protocols, increasing exposure to potential data breaches.

There is also an observed heterogeneity in mandated training and adherence to quality systems across research institutions (universities and MRIs), where some research labs and institutions have more thorough training and protocols in place than others.[3] According to Australia's Chief Scientist Dr Alan Finkel AO, training in research institutions "varies widely in quality and is often seen as a pro forma exercise". [3]

[3] Alan Finkel, To move research from quantity to quality, go beyond good intentions, Nature, Feb 2019

Value and nature of addressing the gap

More widespread adoption of quality management systems and standards by startups and SMEs will drive greater commercialisation success, as companies will be better positioned for investor / partnering discussions, regulatory submissions, and obtaining preferred supplier status in a globally connected market.

Developing greater capabilities in quality management at the basic research level will also drive greater commercialisation outcomes in the long run. Researchers will gain greater credibility among big pharma and medtech companies, and the chances of out-licensing are likely to be higher if the asset and research data have been collated within an accredited quality framework. There were instances highlighted in interviews where research was required to be repeated under GLP processes, slowing commercialisation.

In addition, the current COVID-19 pandemic period has highlighted the value of appropriate quality accreditations when responding to global supply chain disruptions. A number of potential domestic manufacturers of medical equipment and supplies were unable to effectively pivot their operations and contribute to the pandemic response because they lacked ISO13485 and / or GMP certification.[4]

Greater uptake of, and alignment with, quality management systems and standards will help Australia position itself as a home of advanced manufacturing. Meeting appropriate standards will unlock opportunities for Australian manufacturers to integrate further into global markets. Specifically, it will facilitate the expansion of Australia's manufacturing capacity and capability for novel therapy areas such as stem cell and gene therapies, intelligent medical devices and digital health technologies.

Alignment to MTP sector priorities and megatrends

As shown below, the quality management systems and standards skills gap is aligned to three key MTP sector priorities and four megatrends.

[4] MTPConnect COVID-19 Impact Report 2nd Edition, Sector impacts, the road to recovery and future pandemic preparedness, Sep 2020

Sector Priority alignment

Priority 1: Align investment in Knowledge Priorities that meet current and future market needs	A highly productive commercialisation environment requires strong standards of quality assurance, data validity and testing replicability across the MTP sector
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Best-practice quality management and systems are hallmarks of large, professionally managed organisations and are essential capabilities for small enterprises looking to become larger, more stable and successful companies
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	Australia's reputation in advanced manufacturing and its opportunities for integration with global markets will rely on industry-wide excellence in quality management

Megatrend alignment

Precision healthcare	Meeting quality and manufacturing standards is increasingly important in the context of demand for precision medicine solutions and its evolving regulatory frameworks
Digital Evolution	The increasing adoption of digital technology and patient data collection implores the understanding and use of certain protocols (e.g., ISO27001) to safeguard systems against data breaches
Global Biosecurity	Developing greater alignment to quality systems across the sector will also enable more effective pivoting of manufacturing efforts in response to pandemics as has been highlighted by COVID-19
Consumer Control	As consumer-driven products and services such as wearable sensors and in-home monitoring devices continue to grow, quality standards will become increasingly important in winning consumer trust and confidence

Other considerations

There is an opportunity for MTPConnect to collaborate with the Advanced Manufacturing Growth Centre (AMGC) to address this particular skills gap.

Priority Skills Gap Two: Leadership awareness about the importance and best-practice management of cyber security

Theme: Health data & cyber security

Overview

The digital evolution of the healthcare system and development of new areas of medicine such as precision medicine (which involves the capture and analysis of patient genetic data) mean that there is now more private and highly personal data stored on digital systems than ever before. However, the implementation of measures to protect this rapidly growing amount of digital information tends to be highly variable across the sector. As a result, the threat of cyberattacks on organisations, which impact patient safety, privacy and care delivery, has never been higher. In the past year, hospitals, laboratory testing companies and even government departments have all been targeted, resulting in several data breaches that exposed Australians' sensitive health data.[5]

This skills gap particularly relates to:

- A lack of awareness about the importance and value of cyber security amongst senior managers, executives and Board members across the MTP sector ; and
- Skills required in adequate planning and management of cyber security risks, from clinical trial data, to vulnerable medical devices (e.g., connected devices), to electronic medical results, for organisations of all sizes across the MTP ecosystem.

Cyber security needs to be acknowledged as a key business risk rather than an IT risk and ought to be discussed regularly at the senior executive level in order to make this a priority. Collective sharing of experiences across the MTP sector and the healthcare sector more broadly could help raise awareness of the seriousness and severity of impacts.

Stakeholders impacted

The skills gap relating to cyber security leadership awareness and management impacts the entire MTP sector but is most readily observed in the clinical and market segments of the value chain where patient data is most exposed. Senior managers, executives and Board members amongst startups and SMEs have been identified as key stakeholders where more work is required to raise awareness and experience in implementing best-practice management protocols to protect data and devices. By contrast, large MTP companies, healthcare providers and government organisations tend to display greater cyber maturity and more readily employ good cyber security practices. That said, these established companies and institutions are equally or at a greater risk of cyber-attack.

Value and nature of addressing the gap

A 2017 study by Accenture found 16% of consumers surveyed had experienced a breach of their healthcare data, highlighting the vulnerability of the sector and the urgency of the cyber security leadership problem.[6] The cost of failing to promptly address this skills gap could be severe. Cyber-

[5] Webber Insurance Services: The Complete List of Data Breaches in Australia (2018 – 2020)
[6] Accenture Consulting: Consumer Survey on Healthcare Cyber security and Digital Trust (2017)

attacks on MTP companies can threaten consumer / end user trust, erode the value of sensitive IP and cause significant financial losses and disruptions for companies.

COVID-19 has further accelerated the world's transition to digital platforms and is changing how we access healthcare, from digital prescriptions, to tele-health consultations, to remote monitoring of patients in clinical trials. The sector is becoming increasingly reliant on digital tools and with that comes greater exposure to cyber risk. For customers to trust these new digital health services, companies need to ensure they have a greater focus on prevention and management of cyber security threats.

In addition, there is growing digital interconnectedness between medical records, prescriptions and consumer data from digitally enabled medical devices and wearables. It is vital for MTP sector organisations to collaborate with public and private healthcare providers and government in mitigating cyber security risks.

Alignment to MTP Sector Priorities and megatrends

Sector Priority alignment	
Priority 1: Align investment in Knowledge Priorities that meet current and future market needs	Robust and reliable cybersecurity practices are essential to strengthening Australia's capabilities in data science, which is a current MTP Knowledge Priority and a national priority
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Building awareness of cyber security among SME business leaders will enable them to embed cyber security principles and best practices within their business processes and products from early on
Priority 5: Support the development of digital healthcare solutions, devices and data analytics	Reliable cyber security protocols are critical for creating society-wide trust in digital healthcare solutions and are crucial for broad scale adoption

Megatrend alignment

Digital Evolution	The ongoing development of digital health solutions comes with inherent risk, which must be carefully balanced to protect patient data and ensure patient safety
Precision Healthcare	The growing demand for precision healthcare solutions involves the collection, storage, and analysis of patients' genetic data which is at high risk of malicious attack, emphasising the need for cybersecurity leadership, awareness and management protocols
Consumer Control	Growing adoption of personal health technology (e.g., in-home sensors, wearables) increases personal data capture that demands best-practice security and safeguarding

Other considerations

There is an opportunity for MTPConnect to collaborate with the Australian Cyber Security Growth Centre (AustCyber) to address this particular skills gap.

Whilst cyber security is more than just an IT issue for businesses, the use of antiquated IT platforms amongst many MTP organisations exacerbates the risk. For example, many parts of Australia's healthcare delivery system are still running outdated, legacy operating systems that can be easily targeted by hackers. [7]

[7] D. Bushell-Embling, 'Health systems struggle to keep up with hackers', Hospital Health, May 2020

Priority skills gap three: Strategic design of clinical trials to meet regulatory and payer needs

Theme: Clinical trials / Commercialisation

Overview

Australia is globally regarded as an attractive destination for clinical trials.[8] The research environment is underpinned by high-quality scientists, physicians, and healthcare professionals, as well as world-class clinical trial research infrastructure and globally competitive R&D tax incentives.[9]

Despite excellence in the clinical research environment, there is a notable skills gap amongst R&D-intensive MTP startups / SMEs in clinical trial design for optimising market access and beneficial commercial outcomes. Specifically, the skills gap relates to:

- Inadequate expertise in strategically designing clinical trials that take into account, from an early stage, the downstream requirements for regulatory and reimbursement approvals
- A lack of understanding around the level and type of clinical evidence required to demonstrate efficacy of the intervention

As a result, MTP companies need the capabilities to design clinical trials with the end-goal of regulatory and payer approval considered from the earliest stages of trial design. Stakeholder consultations have highlighted that many SMEs and startups often have to conduct additional work after receiving feedback from regulatory bodies such as the TGA / FDA or potential licensing partners in order to collate the necessary clinical evidence required for approval.

Stakeholders impacted

Large pharma and medtech companies are typically experienced at strategically designing their clinical trials programs, and can leverage their global networks and expertise when required. However, the skills gap relating to strategic design of clinical trials is particularly evident within startups and SMEs across the pharma / biotech and medtech sectors. The path to late-stage clinical trials and regulatory approval can be complex and expensive and SMEs tend to lack the expertise to anticipate regulatory and payer requirements when designing their clinical trial programs.

Value and nature of addressing the gap

Clinical trials currently contribute >$1 billion to the Australian economy. Whilst much of this contribution is from globally sponsored trials operated by large pharma and medtech companies, there is still significant value lost in inappropriately designed studies by locally designed trials. Improving the quality and efficiency of these clinical trials conducted through more strategic early stage design can further increase the overall economic contribution of clinical trials.

Stakeholder consultations suggested that startups and SMEs tend to focus heavily on product design and prototype development in the first instance. Consideration of regulatory affairs comes second to this. This can result in wasted time, efforts and resources if the clinical trial results prove to be insufficient for regulatory approval. Furthermore, a significant amount of product development time

[8] MTPConnect, Clinical Trials in Australia: The economic profile and competitive advantage of the sector, 2017
[9] Austrade, Clinical Trials Capability Report, 2018

and patent life (sometimes up to 2-3 years) may be wasted if clinical studies are conducted without proper understanding of regulatory requirements.

Improved capabilities in strategic clinical trial design by startups and SMEs across the sector will drive faster and more effective commercialisation of therapeutics and medical devices. Sophisticated clinical trial designs that incorporate regulatory and reimbursement needs for both domestic and international markets are also likely to facilitate earlier market access to potentially lifesaving therapies and devices.

Alignment to MTP sector priorities and megatrends

Although this skills gap is not directly aligned with specific megatrends due to its general nature, it is an important one that underpins MTP sector priorities. As shown below, the ability to strategically design clinical trials is aligned with three sector priorities.

Sector Priority alignment	
Priority 2: Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials	Clinical trials that are strategically designed to meet regulatory and reimbursement requirements will increase commercialisation outcomes throughout the ecosystem
Priority 3: Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies	Strategically designed clinical trials will enable the SME sub-sector to increase their chances of commercialising their products
Priority 4: Strengthen Australia as an attractive clinical trial research destination	More efficient design of clinical trials will enable greater throughput and strengthen Australia's reputation as an attractive clinical destination

3. CONCLUSION

In summary, three high priority skills gaps were identified during Phase 1 of the skills gaps analysis process:

- Understanding of quality management systems and protocols;
- Leadership awareness about the importance and best-practice management of cyber security; and
- Strategic clinical trial design to meet regulatory requirements and payer needs.

Addressing these priority skills gaps can unlock significant value for the MTP sector and impact a broad cross-section of the MTP value chain. These skills are not currently addressed by existing REDI programs and can be reasonably addressed within the next 12 to 18 months. As a next step, MTPConnect will be developing learning outcomes and competencies for these three priority skills gaps in order to inform the first round of Pillar Two RFPs.

In addition to the above, a list of 13 other skills gaps were identified in Phase 1 based on their alignment with sector priorities and megatrends, as well as the breadth and depth of their impact.

MTPConnect will continue to assess a broader and more comprehensive range of skills gaps across the sector for discussion in the final report that will be published in February 2021.

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APPENDICES

Appendix 1: The scoring matrix

	Description	Scoring matrix		
		1	2	3
Alignment with Sector Priorities	Alignment of the skills gap with the identified Sector Priorities (see SCP 2020 for more detail)	Gap impacts 1-2 of the Sector Priorities	Gap impacts 3-4 of the Sector Priorities	Gap impacts 5-7 of the Sector Priorities
Alignment with megatrends	Alignment of the skills gap with the nine global megatrends that are expected to have a significant impact on sector growth and innovation (see SCP 2020 for more detail)	Gap directly relates to 1-2 of the megatrends	Gap directly relates to 3-5 of the megatrends; or A gap cannot be assessed against megatrends*	Gap directly relates to 6-9 of the megatrends
Breadth of impact of the skills gap	The extent of impact of skills gaps across different parts of the MTP value chain and sub-sectors	Gap is experienced only in one segment of the value chain	Gap is experienced across two segments of the value chain	Gap is experienced in three or four segments of the value chain
Depth of impact of the skills gap	The value that can be achieved by addressing the skills gap (e.g., in regards to economic benefits, social benefits, or health outcomes)	• Gap has low likelihood of causing value loss or time delays, or • Carries a limited opportunity cost of not addressing, or • Has few jobs and public health implications	• Gap has medium likelihood of causing value loss or time delays, or • Carries some opportunity cost of not addressing, or • Has moderate jobs and public health implications	• Gap has high likelihood of causing value loss or time delays, or • Carries considerable opportunity cost of not addressing, or • Has major jobs and public health implications

Note: *a score of 2 is given to skills gaps that cannot be assessed against a megatrend due to the general nature of the gap. This methodology ensures that a particular skills gap is not disadvantaged in scores

Appendix 2: Skills gaps detailed scoring breakdown

	Sector priority alignment	Megatrend alignment	Value chain breadth of impact	Depth of impact (value of impact)	Addressed by REDI	Ease of addressing
Understanding of quality management, protocols and systems	2	2	3	2	No	Easy
Leadership awareness about the importance and best-practice management of cyber security	2	2	2	3	No	Easy
Strategic clinical trial design to address regulatory and payer needs	2	2*	3	2	No	Easy
Capability gap in design and use of AI within MTP	3	2	3	3	No	Hard
Big data capture, management and analysis capability	3	2	3	2	No	Moderate
Lack of clinical and technological capability in genomics and other '-omics'	1	2	3	3	No	Hard
Expertise in health economics, particularly across medtech and digital health	2	2	2	3	No	Moderate
Shortage of pharmacologists and toxicologists	1	2*	3	3	No	Hard
Shortage of industry professionals with end-to-end translational experience	2	2*	3	3	No	Hard
Identifying unmet market need and understanding the clinical context	2	2*	3	3	Yes	*n/a*
Entrepreneurial mindset & risk tolerance	2	2*	3	3	Yes	*n/a*
Procuring investment, funding and / or industry collaboration	2	2*	3	3	Yes	*n/a*
Understanding of end-to-end product development pathway	2	2*	3	2	No	Hard
Understanding the payer and the reimbursement pathway and requirements	2	2*	3	2	Yes	*n/a*
Expertise in IP strategy and pathways	2	2*	3	3	Yes	*n/a*
Expertise in product design including understanding of the end-user	2	2*	3	3	Yes	*n/a*

Key: Top priority skills gaps

Note: * Consideration of megatrends is not relevant for these skills gaps due to their general nature so they have been given a score of two so as to not disadvantage them with respect to other gaps

Appendix 3: Glossary of terms

AI	Artificial Intelligence
AMGC	Advanced Manufacturing Growth Centre
FDA	U.S. Food and Drug Administration
GVA	Gross Value Added
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IP	Intellectual Property
ISO	International Organisation for Standardisation
MRFF	Medical Research Future Fund
MRI	Medical Research Institute
MTP	Medical technology, biotechnology and pharmaceutical
REDI	Research Exchange and Development with Industry Initiative
R&D	Research and Development
RFP	Request For Proposal
SCP	Sector Competitiveness Plan
SME	Small and Medium-sized Enterprises
TGA	Therapeutic Goods Administration

Appendix 4: References

AUTHOR(S)	TITLE	YEAR
Accenture Consulting	Consumer Survey on Healthcare Cyber security and Digital Trust	2017
Austrade	Clinical Trials Capability Report	2018
Hospital Health	"Health systems struggle to keep up with hackers"	2020
MTPConnect	Clinical Trials in Australia: The economic profile and competitive advantage of the sector	2017
MTPConnect	COVID-19 Impact Report 2nd Edition: Sector impacts, the road to recovery, and future pandemic preparedness	September 2020
MTPConnect	Sector Competitiveness Plan 2020	April 2020
Dr Alan Finkel, Nature	"To move research from quantity to quality, go beyond good intentions"	2019
Pharmaceutical Executive	Workforce Readiness: Culture, Tools and Skills Needed by Organizations and Employees to Drive Innovation in Drug Development	2018
Webber Insurance Services	The Complete List of Data Breaches in Australia	2020

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